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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/641,742

08/18/2000

Samuel J. Danishefsky

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04/25/2006

CHOATE, HALL & STEWART LLP  
TWO INTERNATIONAL PLACE  
BOSTON, MA 02110

EXAMINER

CANELLA, KAREN A

ART UNIT

PAPER NUMBER

1643

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/641,742		DANISHEFSKY ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Karen A. Canella		1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 56, 58-62, 65-67, 69-76, 78-81, 84-86 and 88-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 56, 58-62, 65-67, 69-76, 78-81, 84-86, 88-98 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. ____   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08). | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/22/2005</u>  | 6) <input type="checkbox"/> Other: ____                                     |

### DETAILED ACTION

Claims 56, 58, 61, 62, 76 and 78 have been amended. Claims 56, 58-62, 65-67, 69-76, 78-81, 84-86, 88-98 are pending and under consideration.

The rejection of claims 58 and 78 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of applicants amendments.

The rejection of claims 56, 58-62, 65, 67, 70-73, 76, 78-81, 84, 86, 89-92, 95, 97 and 98 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for multiantigenic glycopeptides comprising pyranose moieties, does not reasonably provide enablement for multi-antigenic glycopeptides comprising furanose moieties, is withdrawn in light of applicants amendments.

Applicants state that there is no disclosure of a glycopeptide substituted with an allyl glycosidic moiety having the structure found on page 10 and in claim 61, section (a). In the event that the pagination of applicants specification differs from the pagination of the specification that the examiner is using a copy of page 10 is provided with this action. Applicant argues that the allyl glycoside of claim 61 is merely an intermediate in the preparation of glycoamino acid. Applicant is reminded that the intended use of a molecule is the enablement that applicant is suggesting for a molecule, but that such an enablement does not influence what is actually disclosed as a chemical structure. "Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments v. LKB Produkter AB*, 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989).

The rejection of claims 56, 58-61, 69, 76, 78-80, 88, 97 and 98 under 35 U.S.C. 102(a) as being anticipated by Danishefsky and Allen (*Angew Chemie*, March 3, 2000, Vol. 39, pp. 836-863, reference of the IDS filed July 1, 2002) is maintained for reasons of record.

Claim 56 is drawn in part to a multi-antigenic glycopeptide, and wherein said multi-antigenic glycopeptide comprises 2 to 25 amino acid residues wherein two or more of said amino

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acids is independently substituted with a glycosidic moiety having carbohydrate determinants which are pyranose moieties. Claim 58 embodies the multi-antigenic glycopeptide of claim 56 wherein the glycopeptide is bound to a suitable carrier protein, peptide or lipid. Claim 59 embodies claim 58 wherein the carrier protein is BSA, poly-lysine or KLH. Claim 60 embodies claim 8, wherein the lipid is tripalmitoyl-S-glyceralcysteinylserine. Claim 61 embodies the multi-antigenic glycopeptide of claim 56 which is made by providing an alkenyl glycoside structure. However, it is noted that claim 61 is a product-by-process claim. The M.P.E.P. states that product by process claims are not limited by the process steps, but by the characteristics of the product. Claim 69 embodies the glycopeptide of claim 56 wherein each occurrence of A is independently Globo-H, fucosyl GM1, KH-1, glycophorin, STN, LeY, N3, Tn, 2-6STn, (2,3)ST or TF. Claim 76 is drawn to a pharmaceutical composition comprising a multi-antigenic glycopeptide, and wherein said multi-antigenic glycopeptide comprises 2 to 25 amino acid residues wherein two or more of said amino acids is independently substituted with a glycosidic moiety having carbohydrate determinants which are pyranose moieties. Claim 78 embodies the pharmaceutical composition of claim 76 wherein the glycopeptide is bound to a suitable carrier protein or lipid. Claim 79 embodies claim 78 wherein the carrier protein is BSA or poly-lysine or KLH. Claim 80 embodies claim 78 wherein the lipid is tripalmitoyl-S-glyceralcysteinylserine. Claim 88 embodies the pharmaceutical composition of claim 76 wherein each occurrence of "A" is independently Globo-H, fucosyl GM1, KH-1, glycophorin, STN, LeY, N3, Tn, 2-6STn, (2,3)ST or TF. Claim 97 embodies the pharmaceutical composition of claim 76 wherein one or more of said immunological adjuvants is bacteria or liposomes. Claim 98 embodies claim 97 wherein the adjuvant is Salmonella minnesota, bacille Calmette-Guerin or QS-21.

Danishesky and Allen disclose clustered glycopeptides, having a peptide backbone, wherein three amino acids are substituted with the glycosidic moieties of Tn, Tf, LeY (pages 855-859), and wherein the clustered glycopeptide is conjugated to a lipopeptide, KLH or BSA (page 856, first paragraph under "Discussion of Early Immunological Results"), thus fulfilling the specific embodiments of a . Danishesky and Allen disclose the injection of the clustered immunoconjugate with an adjuvant such as tripalmitoyl-S-glyceralcysteinylserine and QS-21 ((page 856, first column, lines 1-3 and Table 3) fulfilling the specific embodiments of conjugated to a carrier and a composition comprising an immunological adjuvant. The clustered

glycopeptides fulfill the specific embodiment of a multi-antigenic glycopeptide because each glycopeptide comprises three carbohydrate epitopes. The instant rejected claims do not specify that the multiple epitopes cannot be the same.

The rejection of claims 56, 58, 62, 69, 76, 78-81, 88-90 under 35 U.S.C. 102(a) as being anticipated by Danishefsky et al (WO 99/48515) is maintained for reason of record.

Claim 62 embodies the glycopeptide of claim 56 which is a construct have the structure of a glycopeptide attached to a linker which is attached to a crosslinker having an indicia of "q" wherein "q" can be 0 or 1, wherein said crosslinker is further attached to a carrier. Claim 89 embodies the pharmaceutical composition of claim 81 wherein the carrier is BSA, poly-lysine or KLH. Claim 90 embodies the pharmaceutical composition of claim 81 wherein the carrier is tripalmitoyl-S-glyceralcysteinylserine.

Danishefsky et al disclose the Tn trimer glycopeptide in Figure 20A, wherein said glycopeptide is conjugated to BSA, KLH or tripalmitoyl-S-glyceralcysteinylserine (compounds 3, 4 and 5 in Figure 20A). Danishefsky et al disclose the linker by which the attachment to the carrier is provided in Figure 20C which fulfills the specific embodiments of claim 62, wherein "q" is zero.

The rejection of claims 56, 61, 69, 76 and 78 under 35 U.S.C. 102(b) as being anticipated by Toyokuni and Singha (Chemical Society Reviews, 1995, Vol. 24, pp. 231-242, reference of the IDS filed September 18, 2003) is maintained for reasons of record.

Toyokuni and Singha disclose the Tn antigen cluster of Scheme 11, compound 19 (page 237), which fulfill the requirement of a multi-antigenic glycopeptide because it contains three TN antigens attached to three amino acids. Toyokuni and Singha also fulfill the specific embodiments of claim 61 because the product would have the same structure as that made by the method of claim 61. Toyokuni and Singha disclose that a spacer was installed in order to preclude any interaction between the Tn antigens and the carrier molecule (page 235, second column, lines 3-5 under the heading "Linear Amplification"). Toyokuni and Singha disclose that compound 19 was linked to OSA (page 239, lines 1-3 under the heading of "Semi-Synthetic Tn Vaccines") thus fulfilling the specific embodiments of claims 76 and 78.

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Applicant argues that none of the cited references can read on the instant claims because the claims carry the provision, "if for each occurrence of n,  $n=0$ , at least one occurrence of A has a different structure for other occurrences of A". This has been considered but not found persuasive. The structure disclosed by Danishefsky and Allen in Scheme 21, page 856, indicates that the  $R=H$  for structures 100 and 104. The structure disclosed by Toyokuni and Singha also indicates a methylene group after the oxygen atom attached to the pyranose ring on the bottom, right of page 1120. The structures disclosed by Danishefsky et al (WO 99/48515) also have a methylene group after the sugar of the pyranose ring and the peptide backbone. For all of the above references, there is a methylene group between the pyranose ring and the peptide and therefore the above provision does not apply because n is 1, not 0.

The provisional rejection of claims 56, 58-62, 65-67, 69-76, 78-81, 84-86 and 88-98 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 118-198 of copending Application No. 10/209,618 and claims 1-36 of copending Application No. 10/728,041 is maintained for reasons of record.

All other rejections and objections as set forth in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828.

The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

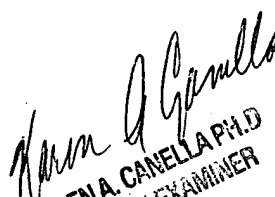
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

4/6/2006

  
KARENA. CANELLA PH.D  
PRIMARY EXAMINER